**IN THE UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF ILLINOIS**

**J.B., *a minor*, *by* LINDA LEJUNE,**[1]
***individually as legal custodian and***
***next friend of J.B.*,**

**Plaintiffs,**

**v.**

**ABBOTT LABORATORIES INC.,**

**Defendant.** **No. 13-cv-326-DRH-SCW**

**MEMORANDUM AND ORDER**

**HERNDON, Chief Judge:**

## I. INTRODUCTION

Pending before the Court is defendant Abbott Laboratories Inc.'s (Abbott) motion for summary judgment and brief in support thereof (Doc. 122). Abbott moves for summary judgment pursuant to FEDERAL RULE OF CIVIL PROCEDURE 56 on all of plaintiff John Bonner's (Bonner) claims. Bonner opposes Abbott's requested relief (Doc. 136) (filed under seal). For all of the reasons stated below, Abbott's motion is **GRANTED in part and DENIED in part**.

## II. UNDISPUTED FACTS

Bonner was born with spina bifida, a spinal cord defect, on December 15, 1994, in Louisiana. Bonner attributes his spina bifida, and other alleged physical

[1] The Court notes the parties refer to Linda Lejune as "Linda LeJeune." The Court's spelling is based on the relevant complaint. Bonner is no longer a minor. The Court questions whether a custodian is still required.

and cognitive injuries, to Bonner's mother Chantele Bonner's (Chantele) use of Abbott's anti-epilepsy drug (AED) Depakote[2] while pregnant with Bonner.

Dr. Riad Hajmurad first prescribed Depakote to Chantele in approximately 1989. In approximately 1990, Chantele stopped seeing Dr. Hajmurad and began seeing Dr. George Isaacs, who continued to prescribe Depakote to Chantele from approximately 1990-1995.

In 1994, the Warnings section of the Depakote prescribing information (the 1994 Label) stated the following, in part:

> *Usage in Pregnancy*: ACCORDING TO PUBLISHED AND UNPUBLISHED REPORTS, VALPROIC ACID MAY PRODUCE TERATOGENIC EFFECTS IN THE OFFSPRING OF HUMAN FEMALES RECEIVING THE DRUG DURING PREGNANCY.
> THERE ARE MULTIPLE REPORTS IN THE CLINICAL LITERATURE WHICH INDICATE THAT THE USE OF ANTIEPILECTIC DRUGS DURING PREGNANCY RESULTS IN AN INCREASED INCIDENCE OF BIRTH DEFECTS IN THE OFFSPRING. ALTHOUGH DATA ARE MORE EXTENSIVE WITH RESPECT TO TRIMETHADIONE, PARAMETHADIONE, PHENYTOIN, AND PHENOBARBITAL, REPORTS INDICATE A POSSIBLE SIMILAR ASSOCIATION WITH THE USE OF OTHER ANTIEPILEPTIC DRUGS. THEREFORE, ANTIEPILEPTIC DRUGS SHOULD BE ADMINISTERED TO WOMEN OF CHILDBEARING POTENTIAL ONLY IF THEY ARE CLEARLY SHOWN TO BE ESSENTIAL IN THE MANAGEMENT OF THEIR SEIZURES.
> THE INCIDENCE OF NEURAL TUBE DEFECTS IN THE FETUS MAY BE INCREASED IN MOTHERS RECEIVING VALPROATE DURING THE FIRST TRIMESTER OF PREGNANCY. THE CENTERS FOR DISEASE CONTROL (CDC) HAS ESTIMATED THE RISK OF VALPROIC ACID EXPOSED WOMEN HAVING CHILDREN WITH SPINA BIFIDA TO BE APPROXIMATELY 1 to 2%.[footnote deleted].
> OTHER CONGENITAL ANOMOLIES (EG, CRANIOFACIAL DEFECTS, CARDIOVASCULAR MALFORMATIONS AND ANOMALIES INVOLVING VARIOUS BODY SYSTEMS), COMPATIBLE AND INCOMPATIBLE WITH LIFE, HAVE BEEN

[2] "Depakote" refers to Abbott's group of prescription drugs with the basic ingredient valproic acid. Depakote is also sometimes referred to by the chemical names "valproic acid" or "valproate."

> REPORTED. SUFFICIENT DATA TO DETERMINE THE INCIDENCE OF THESE CONGENITAL ANOMALIES IS NOT AVAILABLE.
> THE HIGHER INCIDENCE OF CONGENITAL ANOMOLIES IN ANTIEPILEPTIC DRUG-TREATED WOMEN WITH SEIZURE DISORDERS CANNOT BE REGARDED AS A CAUSE AND EFFECT RELATIONSHIP.
>
> . . .

(*Physicians' Desk Reference* at 414, Doc. 122-3, p. 3; Doc. 136-5, Ex. A 26, pp. 34-41).

## III. LEGAL STANDARD

This case is before the Court pursuant to diversity jurisdiction. *See* 28 U.S.C. § 1332(d)(2) & (d)(5). The parties do not dispute that the federal summary judgment standard applies. *See* FED. R. CIV. P. 56. Summary judgment is proper where the movant shows "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(a); *accord Celotex Corp. v. Catrett*, 477 U.S. 317, 322–23 (1986). A genuine issue of triable fact exists if, "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Pugh v. City of Attica, Ind.*, 259 F.3d 619, 625 (7th Cir. 2001) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)).

The movant bears the burden of establishing the absence of fact issues and entitlement to judgment as a matter of law. *Santaella v. Metro. Life Ins. Co.*, 123 F.3d 456, 461 (7th Cir. 1997) (citing *Celotex*, 477 U.S. at 323). Once the moving party has set forth the basis for summary judgment, the burden then shifts to the nonmoving party who must go beyond mere allegations and offer specific facts

showing that there is a genuine issue for trial. FED. R. CIV. P. 56(e); *see Celotex*, 477 U.S. at 323–24. The nonmoving party must offer more than "[c]onclusory allegations, unsupported by specific facts," to establish a genuine issue of material fact. *Payne v. Pauley*, 337 F.3d 767, 773 (7th Cir. 2003) (citing *Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 888 (1990)).

A party will successfully oppose summary judgment only if it presents, "definite, competent evidence to rebut the motion." *EEOC v. Sears, Roebuck & Co.*, 233 F.3d 432, 437 (7th Cir. 2000). The Court considers the record in the light most favorable to the nonmoving party, and draws all reasonable inferences in the nonmovant's favor. *Lesch v. Crown Cork & Seal Co.*, 282 F.3d 467, 471 (7th Cir. 2002). However, the Court accepts the nonmoving party's version of any disputed fact only if supported by relevant, admissible evidence. *Bombard v. Fort Wayne Newspapers, Inc.*, 92 F.3d 560, 562 (7th Cir. 1996).

## IV. LAW AND APPLICATION

When sitting in diversity, a federal court must apply the choice-of-law rules of the forum state in which it sits to determine the applicable substantive law. *Tanner v. Jupiter Realty Corp.*, 433 F.3d 913, 915 (7th Cir. 2006). In tort actions such as this one, Illinois courts apply the substantive law of the forum with the "most significant relationship" to the case. *Id.* (citing *Esser v. McIntyre*, 661 N.E.2d 1138, 1141 (Ill. 1996)). The parties agree that the substantive law of Louisiana governs this dispute.[3]

[3] Bonner argues Illinois law governs the issue of punitive damages. The Court does not comment on this assertion at this time.

The Louisiana Product Liability Act (LPLA) "establishes the exclusive theories of liability for manufacturers for damage caused by their products." LA. REV. STAT. § 9:2800.52. Pursuant to the LPLA, "[t]he manufacturer of a product shall be liable to a claimant for damage caused by a characteristic of the product that renders the product unreasonably dangerous." LA. REV. STAT. § 9:2800.54(A). Specifically, a product can be deemed "unreasonably dangerous:" 1. in construction or composition; 2. in design; 3. because an "adequate warning about the product has not been provided;" or 4. because of non-conformity with a manufacturer's express warranty. LA. REV. STAT. § 9:2800.54(B).

**1. Failure to Warn**

Abbott seeks judgment as a matter of law as to Bonner's failure to warn claim stating it warned Chantele's prescribing physician about the risk of spina bifida. The LPLA defines "adequate warning" as:

> [A] warning or instruction that would lead an ordinary reasonable user or handler of a product to contemplate the danger in using or handling the product and either to decline to use or handle the product or, if possible, to use or handle the product in such a manner as to avoid the damage for which the claim is made.

LA. REV. STAT. § 9:2800.53(9).

"Louisiana applies the 'learned intermediary doctrine' to products liability claims involving prescription drugs." *Stahl v. Novartis Pharm. Corp.*, 283 F.3d 254, 265 (5th Cir. 2002) (citing *Anderson v. McNeilab, Inc.*, 831 F.2d 92, 93 (5th Cir. 1987)). Thus, a drug manufacturer discharges its duty to consumers when it reasonably informs prescribing physicians of the dangers of harm from a drug. *Id.* When the learned intermediary doctrine is applicable, a two-prong test

governs LPLA inadequate-warning claims. First, the plaintiff must show that the defendant inadequately warned the physician of a risk associated with the product that was not otherwise known to the physician. *Id.* (citing *Willett v. Baxter Int'l. Inc.*, 929 F.2d 1094, 1098 (5th Cir. 1991)). And second, the plaintiff must demonstrate that the defendant's failure to adequately warn the physician was "both a cause in fact and the proximate cause of the plaintiff's injury." *Id.*

Under the first prong, a mere reference to an adverse effect does not necessarily demonstrate the warning at issue is "adequate" under the LPLA. Rather,

> [A] warning regarding a particular adverse drug reaction is adequate as a matter of law if the package insert clearly and unambiguously mentions the specific ailment suffered by the plaintiff *AND* the plaintiff's prescribing physician *unequivocally* testifies that the information provided in the warning was adequate to provide that physician with a reasonable understanding of the risks involved.

*Id.* (emphasis in original) (citing *White v. Slidell Mem'l Hosp. & Med. Ctr.*, No. CIV. A. 89-2691, 1990 WL 111447 (E.D. La. July 26, 1990) (Sear, J.); *Mikell v. Hoffman-Laroche, Inc.*, 94-0242, (La. App. 1 Cir. 12/22/94), 649 So. 2d 75, 80; *Cobb v. Syntex Labs., Inc.*, 444 So. 2d 203, 205-06 (La. Ct. App. 1983); *Timm v. Upjohn Co.*, 624 F.2d 536, 539 (5th Cir. 1980)).

Abbott states it is undisputed that the 1994 Label warned that Depakote presented a risk of having a child born with spina bifida and also that Dr. Isaacs understood that the label warned of such risk when he prescribed Depakote to Chantele.

As for Chantele's prescribing physicians, Dr. Hajmurad generally answered yes, that it is important to have "accurate" and "complete" "facts" about the risks of a particular drug and that the manufacturer of the drug is one of the "sources of information about the risks about their drugs." When asked, "if Abbott was aware of medical literature back in the 1980s that indicated that Depakote was more teratogenic [likely to cause birth defects] than other AEDs, is that something you would have expected them to have told you as a prescribing doctor?" Dr. Hajmurad answered, "[i]t should be," and that further this would "definitely" change his "prescribing behavior of Depakote."

And when asked, "[i]f information about a drug exists that it is more teratogenic than other drugs that treat a similar condition, that's something you would want to know as a prescribing doctor?" Dr. Hajmurad answered, "Yes." Similarly, when asked, "[s]o, if you had been made aware in the late 1980s or 1990 that Depakote was associated with a higher risk of birth defects than other AEDs, that is something you would have discussed with [Chantele]?" Dr. Hajmurad answered, "I would have." And finally, Dr. Hajmurad answered affirmatively that "[i]f there was language in the 1989 Depakote PDR advising physicians not to prescribe Depakote for women of child-bearing years unless every other antiepileptic drug was ineffective," he would have followed that directive. And that that is his practice today. (Doc. 136-9, Ex. A-39, pp. 30-42).

Dr. Isaacs prescribed Chantele Depakote from approximately 1990-1995. At Dr. Isaac's deposition, Dr. Isaac stated he relies on warning labels, such as the

1994 Label, to in part educate his prescribing decisions and expects the information provided to be up-to-date and accurate. Dr. Isaacs answered yes, that if he had been made aware in 1994 that Depakote was associated with a higher risk of birth defects than other AEDs [assuming the truth of this statement], he would have advised Chantele about reasonable alternative AEDs, if available, and prescribed "some other combination, if not one drug."

As to the 1994 Label, the following exchange took place:

> Q. In fact, the language that Abbott uses in its 1994 label doesn't disclose anything about whether Depakote poses a higher or a lower risk of birth defects than other AEDs. Is that right?
>
> A. According to this, I think that's correct.

Additionally, after being read the portion of the 1994 Label which states, "[a]lthough data are more extensive with respect to trimethadione, paramethadione, phenytoin and phenobarbital, reports indicate a possible similar association [of birth defects] with the use of other antiepileptic drugs," Dr. Isaacs stated he believed the "similar association" included Depakote and that he trusted this information was accurate and truthful as of that time. As to the statement, "the higher incidence of congenital anomalies in antiepileptic drug-treated women with seizure disorders cannot be regarded as a cause-and-effect relationship," Dr. Isaacs was asked, "[s]o does this tell you that there's not necessarily a causal relationship between Depakote and birth defects?" Dr. Isaacs answered yes, and also stated that it Abbott had been aware as of 1994 that the medical literature indicated Depakote was actually causally related to birth defects, he would have

taken that information into account in his prescribing habits (Doc. 136-9, Ex. A-40, pp. 43-61).

Bonner argues that the 1994 Label misled Chantele's prescribing physician as it provided inaccurate, incomplete, and misleading information. Thus, the 1994 Label did not adequately provide a "reasonable understanding of the risks involved." *See Stahl*, 283 F.3d at 267.

In reliance on *Cowart v. Avondale Indus., Inc.*, 01–894 (La. App. 4 Cir. 7/3/01), 792 So. 2d 73, Abbott argues it had no duty to warn of comparative risks. In *Cowart,* one of the plaintiffs worked as a chipper and grinder in Avondale Industries' (Avondale) foundry. He alleged contraction of silicosis form exposure to silica-containing products. Unimin Corporation (Unimin) was brought in as a defendant for its alleged manufacture of silica sand and as a successor in interest to a manufacturer. In part, the plaintiffs argued Unimin Corporation owed a duty to Avondale to make it aware of safer alternative products. *Id.* at 73-74.

In rejecting this contention, the court noted, "the LPLA section on inadequate warnings does not mention any requirement that a manufacturer advise the users of its product of any information regarding the existence of safer alternative products. Once having found Avondale to be a sophisticated user, the trial court should have granted Unimin's motion for summary judgment and dismissed plaintiff's claims against it." *Id.* at 77.

Abbott cites *Cowart*, and other decisions applying non-Louisiana law, in support of the proposition that a manufacturer generally does not have a duty to

provide a comparison of its drugs with other "safer" alternative products, i.e., advertise or sell another manufacturer's product. *See Pluto v. Searle Labs.*, 690 N.E.2d 619, 621 (Ill. App. 1997) ("Searle is under no duty to provide information on other products in the marketplace. Such a duty would require drug manufacturers to rely upon the representations made by competitor drug companies"); *Ackley v. Wyeth Labs., Inc.*, 919 F.2d 397, 405 (6th Cir. 1990) ("The manufacturer is obligated to make a reasonable disclosure of all the risks inherent in its own drug. It is not obligated to provide a comparison of its drug with others." (citation omitted)); *Barnes v. Kerr*, 418 F.3d 583, 590 (6th Cir. 2005) ("Although a product manufacturer generally has a duty to warn of the dangers of its own products, it does not have a duty to warn of the dangers of another manufacturer's products."); *Adamson v. Ortho-McNeil Pharm., Inc.*, 463 F. Supp. 2d 496, 504 (D.N.J. 2006) (Wolfson, J.) ("Plaintiff does not cite a single case to suggest the existence of such a duty and courts have routinely held that competitors have no duty to advertise or sell a competitor's products.").

The Court does not agree that *Cowart* and the cases cited above interpreting non-Louisiana law call for judgment in Abbott's favor as to Bonner's failure to warn claim. The above cases do not appear to involve warnings that included comparative information. And further, Bonner's failure to warn claim does not arise solely from the alleged comparative information included in the 1994 Label.

An "adequate" warning is one "that would lead an ordinary reasonable user or handler of a product to contemplate the danger in using or handling the product." LA. REV. STAT. § 9:2800.53(9). Bonner theorizes that once Abbott included comparative information in its label, it assumed a duty to ensure that the information provided was not inaccurate or misleading and thus "adequate to provide that physician with a reasonable understanding of the risk involved." *Stahl*, 283 F.3d at 265. Bonner further contends Abbott's duty to provide accurate and up-to-date information applies to all of its 1994 Label statements. Abbott has not presented the Court with authority capable of convincing it that Bonner's failure to warn claim is barred under Louisiana law.

In reviewing Bonner's evidence offered in support of its contention that Abbott's 1994 label is inadequate, the Court finds summary judgment in Abbott's favor is not warranted. By way of example, Dr. Lemuel Moye, an M.D. and Ph.D. in Community Sciences- Biostatistics, concludes "[t]he scientific evidence *from the 1980s* to the present also establishes Depakote as more toxic to the fetus than alternative drugs in general use during the last three decades" (Doc. 136-14, Ex. F, p. 32) (emphasis added).[4]

As to the second prong, Bonner must demonstrate that "a proper warning would have changed the decision of the treating physician, *i.e.* that but for the inadequate warning, the treating physician would not have used or prescribed the product." *Willett v. Baxter Intern., Inc.*, 929 F.2d 1094, 1099 (5th Cir. 1991).

[4] The Court notes that Abbott moves to exclude the testimony of Cheryl D. Blume Ph.D. As this motion is not yet fully ripe, the Court does not expressly rely on Dr. Blume's opinions in rendering its instant decision.

Bonner theorizes that the 1994 Label is inadequate because it is inaccurate and misleading. Bonner has presented evidence demonstrating a genuine factual dispute exists as to this contention. And to summarize, Chantele's prescribing physician in 1994, Dr. Isaacs, testified that if the state of the medical knowledge was as alleged in 1994 and made known to him, it would have changed his prescribing habits of Depakote. Bonner has demonstrated a triable issue of fact exists as to causation.

**2. Other LPLA Causes of Action**

Abbott additionally seeks summary judgment as to claims of manufacturing defects, LA. REV. STAT. § 9:2800.55, design defect, LA. REV. STAT. § 9:2800.56, and breach of express warranty, LA. REV. STAT. § 9:2800.58. Bonner states he does not bring claims based on a manufacturing or design defect, and thus summary judgment is granted to Abbott on these claims, solely as to this case.

As to a breach of express warranty claim, express warranty, "means a representation, statement of alleged fact or promise about a product or its nature, material or workmanship that represents, affirms or promises that the product or its nature, material or workmanship possesses specified characteristics or qualities or will meet a specified level of performance." LA. REV. STAT. § 9:2800.53(6). "A product is unreasonably dangerous when it does not conform to an express warranty made at any time by the manufacturer about the product if the express warranty has induced the claimant or another person or entity to use

the product and the claimant's damage was proximately caused because the express warranty was untrue." La. Rev. Stat. § 9:2800.58.

Abbott argues Bonner has not offered evidence that Abbott made an express warranty to Chantele or Dr. Isaacs. Bonner cites the 1994 Label as evidence of an express warranty. Specifically, Bonner cites the comparative language referenced above and these statements: "[t]he higher incidence of congenital abnormalities in antiepileptic drug-treated women with seizure disorders cannot be regarded as a cause and effect relationship," and "sufficient data to determine the incidence of these congenital anomalies is not available." These are affirmative representations about Depakote's characteristics or qualities. Bonner offers evidence that certain representations made in the 1994 Label are misleading and inaccurate. Dr. Isaacs testified he relies on warning information, such as the 1994 Label, when making prescribing decisions, and in turn, Chantele testified she relies on her doctor. Thus, a factual dispute exists as to Bonner's express warranty claim.

## V. CONCLUSION

For all of the above stated reasons, Abbott's motion for summary judgment is **GRANTED in part and DENIED in part** (Doc. 122). Summary judgment is granted in Abbott's favor as to claims of a manufacturing defect or design defect under the LPLA, solely as to Bonner, 13-cv-326-DRH-SCW. Summary judgment is denied as to Bonner's failure to warn and breach of express warranty claims under the LPLA. The Court reminds the parties that the deadline for filing *Daubert*, dispositive, and *in limine* motions has passed. The pending *Daubert*,

dispositive, and *in limine* motions will be fully ripe on **April 18, 2014**.[5] Oral argument on all pending motions will be held at the final pretrial conference set for **May 1, 2014**. The Court refers the parties to the undersigned's case management procedures for information pertaining to the required proposed Final Pretrial Order. As to the substance of the proposed Final Pretrial Order, the Court reminds the parties that the Final Pretrial Order supersedes the pleadings. *See Gorlikowski v. Tolbert*, 52 F.3d 1439, 1443–44 (7th Cir. 1995). Jury selection begins **May 12, 2014**. Opening statements and evidence begin **May 14, 2014**, at 9:00 a.m. with the undersigned presiding.

**IT IS SO ORDERED.**

Signed this 14th day of April, 2014.

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**Chief Judge**
**United States District Court**

[5] As the pending *Daubert*, dispositive, and *in limine* motions are not fully ripe, this Order of course does not comment as to the merits of said pending motions.